



Facultad de Estudios Superiores

IZTACALA



TITLE OF THE STUDY:

ACCEPTABILITY, EFFICACY AND MODERATORS OF CLINICAL
CHANGE OF A TRANSDIAGNOSTIC GUIDED INTERNET-DELIVERED
FOR EMOTIONAL, TRAUMA AND STRESS-RELATED DISORDERS:
RANDOMIZED CONTROLLED TRIAL

DATE: December, 2021



INFORMED CONSENT

Dear participant, you have been invited to a scientific study entitled: "Acceptability, Efficacy and Moderators of Clinical Change of a Transdiagnostic Guided Internet-Delivered for Emotional, Trauma and Stress-Related Disorders: Randomized Controlled Trial" that is carried out by members of the Laboratory of Psychology and Technological Innovation (LABPSIIT) of the Faculty of Higher Studies *Iztacala* of the National Autonomous University of Mexico, whose principal investigator is Dr. Anabel de la Rosa Gómez. The purpose of this notice is to inform you of the objectives of the project as well as the confidential use of your data derived from the study.

The objective of the study is to determine the clinical utility and satisfaction of a self-administered intervention program based on the transdiagnostic approach through a telepsychology system aimed at adults who meet diagnostic criteria for an emotional disorder or derived from a stressful or traumatic event. The clinical evaluation of the users will be carried out in 4 moments (before, after and at six and twelve months after the treatment). The initial evaluation will be carried out by videoconference or by telephone, it will consist of the application of a series of questionnaires that will help to assess their emotional discomfort. Once the evaluation is completed, you will be assigned to one of the study conditions (experimental or waiting list) and you will be registered in the telepsychology system. Participants in the waiting list control group will receive the necessary access data to complete the intervention 2 months after the intervention and will be assigned to the intervention that has shown better results and satisfaction. The intervention will be available via the internet and will consist of 10 interconnected modules to which you will have access when registering on the digital platform; each participant can follow their own pace, the platform will be available 24 hours a day, approximately two months may be required to cover the entire program. All participants may withdraw from treatment at any time.

The requested Personal Data will be processed for research, teaching and statistical purposes. The Personal data will be protected through a code that guarantees their confidentiality. Access to the data will be limited to the main researcher of the study and the management technician of the institutional server housed in the facilities of the Coordination of Distance Education of the Faculty of Higher Studies *Iztacala*, UNAM, with address at Av de los Reyes 1, Tlalnepantla de Baz, México CP 5700. Likewise, the data will be kept during your participation in the intervention and, once concluded, will be kept for an additional period of up to 5 years to later be eliminated in order to avoid improper treatment. The information provided by the Web Application will be treated with all appropriate security measures, in accordance with the principles contained in the Federal Law on Protection of Personal Data Held by Private Parties, its Regulations and the Guidelines of the Privacy Notice of the United Mexican States.

Consequences:

The risks of your participation are minimal, some questions in the questionnaires assess your state of mind and you could relive stressful situations, which could cause you some discomfort or emotional distress. If you prefer, you can skip these questions, although they are important for the purpose of the study. Also, during the treatment sessions you could present a greater manifestation of emotions or feelings, do not be alarmed, it is normal because the central mechanism of the intervention is emotional regulation in the face of various vicissitudes of life. If you experience acute discomfort, notify your psychological advisor or the principal investigator of the study immediately.



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Benefits:

If you agree to participate, you will join a free psychological support program through a self-administered program of 10 interactive modules and an online support service (by videoconference) by supervised and qualified psychologists, who will clarify any questions you may have about the content of the modules or tasks to be carried out. For more questions, you can contact us by mail to Dr. Anabel de la Rosa Gómez, responsible for the project: anabel.delarosa@iztacala.unam.mx

To begin, we ask you to answer a series of questionnaires that will be presented below, which will take about 15 minutes. There are no right or wrong questions, so please answer as honestly as possible.

"I have read this informed consent document, I have understood the explanations provided in it about the objective of the research project. I also understand that, at any time and without giving any explanation, I can revoke the consent that I now present. I have also been informed and understand that the data I provide will be protected and used only for academic and research purposes. I voluntarily consent to my participation in the intervention program under the characteristics that operate in it and that were previously mentioned. I understand that I have the right to withdraw my participation at his own will".

You may receive a copy of this informed consent to your provided email and may request its cancellation through the following email: labpsiit@iztacala.unam.mx

I freely agree to participate in the study: I ACCEPT / I DO NOT ACCEPT